

**Application No.: 10/646,852**  
**Filing Date: August 22, 2003**

## **REMARKS**

Claims 2-8, 10-13, 16-22, 27, and 33-45 are currently pending. No claims are amended herein. No new matter is added.

### **Priority**

In the Office Action the Examiner again conclusively stated that "It is noted that provisional application 60/405791 does not correspond to the current application. Specifically, 60/405791 is not directed to the addition of a monovalent salt. Applicant is not entitled to the priority date of the provisional application." Office Action, page 2. Applicant respectfully disagrees with this conclusory statement and notes that the Examiner did not provide a claim by claim analysis of the priority. Even assuming *arguendo* that the provisional application does not disclose addition of a monovalent salt, at least Claims 38, 2-8, 10-13, 16, and 27 are entitled to priority because they do not recite a monovalent salt.

Applicant notes that the Examiner did not respond to the Applicant's previous arguments regarding priority and that Carr is an improper reference under 35 U.S.C. § 103 for claims entitled to the priority date of provisional application 60/405791.

### **Carr Does Not Anticipate or Make Obvious Claims 2-8, 10-13, 16-22, and 38-45**

The Examiner rejected Claims 2-8, 10-13, 16-22, and 38-45 under 35 U.S.C. § 102(e) as anticipated by WO 02/096208 to Carr or in the alternative under 35 U.S.C. § 103 as obvious over Carr.

### **Anticipation**

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994).

Applicant also notes that "[i]nherency, however, may not be established by probabilities or possibilities. The fact that a given thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). See also *Tintec Industries, Inc.*

**Application No.: 10/646,852**  
**Filing Date: August 22, 2003**

v. Top-USA Corp., 63 U.S.P.Q.2d 1597, 1599 (Fed. Cir. 2002). When relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art. Ex parte Levy, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added).

In the Final Office Action the Examiner repeated the rationale from the previous Office Action. In responding to the Applicant's arguments, the Examiner found that "Applicant does not exclude the additional steps of Carr" (O.A. at page 4) and "Applicant merely claims 'enhance its ability to emulsify fat.' Applicant does not specifically claim an enhanced emulsion." (O.A. at page 5.)

Applicant respectfully disagrees with the Examiner's findings and characterization of the claim language. First, Applicant submits that Carr does not disclose the steps or order of steps recited in independent Claims 33 and 38. Thus, Carr cannot anticipate even if Applicant does not exclude some steps of Carr.

With regards to the Examiner's finding that an enhanced emulsion is not claimed, Applicant points out that the pending claims are method claims and that enhancing the ability of the protein solution to emulsify fat is a meaningful physical change that must be given patentable weight. Also, Claim 38 recites "mixing the hydrated protein solution with a concentrated fat to form a first food product" and Claim 33 recites "combining the reconstituted skim milk with concentrated milk fat." Further, Claim 39 and its dependents recite forming a first food product that comprises high fat cream. Without the increased emulsion capacity it would not be possible to form a high fat cream from concentrated protein.

Applicant also continues to disagree with the Examiner's characterization of Carr. Example 9 of Carr, relied on by the Examiner, discloses adding fresh cream to fresh skim milk and subsequently adding various compositions of MPC85 to the mixture of fresh cream and fresh skim milk. Carr, page 9, ll. 13-25. Carr is concerned with preparing a dried enhanced-solubility MPC. Carr discloses that "[t]he term 'enhanced solubility' refers to the property of a product which on reconstitution into a 5% w/v solution provides less sediment on centrifugation for 10 minutes at 700g relative to the corresponding product without salt treatment." Carr, page 2. There is no disclosure in Carr regarding emulsification properties.

Again, the Examiner has only provided a conclusory statement which clearly does not meet the required burden for showing inherency. When relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added).

Carr focuses on *enhancing the solubility* of dried MPC. Enhanced solubility and enhanced emulsification are *not* synonymous. Briefly, the highly polar nature of water molecules prevents water from effectively interacting with the distinctly non-polar fat or oil molecules. The polarity differences therefore prevent fats/oils from dissolving in water, and force water and fat/oil to separate into distinct, independent phases, unless stabilized as emulsions by emulsifiers. Emulsifiers are typically molecules with two distinctly different sections:

- A. a highly polar section that interacts with the highly polar water molecules, and
- B. a highly non-polar section that interacts with the non-polar fat/oil

The shape or conformation of the molecule allows both sections to freely interact with components of the respective polarity: i.e. the highly polar section must freely interact with water, while the non-polar section simultaneously must freely interact with the fat/oil phase. Therefore, effective emulsifiers typically have both the correct molecular structure (i.e. both the separate polar and non-polar sections) and the correct conformation (i.e. the correct shape positioning the separate sections so that these sections simultaneously and freely interact with the respective components).

Increasing the solubility of any particular protein does not inherently enhance the ability of that protein to emulsify fat. Indeed, enhancing the solubility of most proteins may proportionally decrease the ability of those proteins to emulsify fat. The solubility of a protein depends upon the protein assuming a conformation that maximizes the exposure of the polar amino acid groups in the protein's primary structure to water. These conformations must simultaneously minimize the surface exposure of the non-polar amino acids, because the inability of non-polar amino acids to interact with water proportionally reduces solubility. Therefore any protein conformation maximizing solubility must fold the non-polar amino acids deep into the protein interior, essentially masking the inherent incompatibility of polar and non-polar

**Application No.: 10/646,852**  
**Filing Date: August 22, 2003**

compounds. Positioning the non-polar amino acids within the protein interior renders these sections incapable of simultaneously interacting with fat. Unable to interact with the fat, these proteins *cannot* effectively act as emulsifiers. Such conformations proportionally increase the solubility of the protein, while simultaneously reducing the ability of that protein to effectively emulsify fat.

Therefore, Carr fails to inherently or explicitly disclose “adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein”. Carr also fails to disclose explicitly or inherently “mixing the hydrated protein solution with a concentrated fat to form a first food product” as recited in Claim 38. Accordingly, because Carr does not teach, inherently or explicitly, each of the elements of the claims, Applicant respectfully request withdrawal of this rejection for at least this reason.

### **Obviousness**

The Examiner also rejected Claims 2-8, 10-13, 16-22, and 38 under 35 U.S.C. § 103 as obvious over Carr.

Carr is cited as a prior art reference under 35 U.S.C. § 102(e) for claims entitled to the priority of the provisional application. As discussed above, these claims include at least Claims 38, 2-8, 10-13, 16, and 27. 35 U.S.C. § 103(c)(1) states:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103(c)(1).

Carr and the present application were both owned or under a common obligation of assignment to Fonterra Co-Operative Group LTD. at the time the claimed inventions were made. The Assignment of the present application to Fonterra Co-Operative Group LTD. is recorded at Reel 014483, Frame 0043. The Applicant for Carr is the New Zealand Dairy Board. In October of 2001 Fonterra Co-Operative Group LTD. was formed by the merger of the New Zealand Dairy Board with the New Zealand Dairy Group and Kiwi Co-operative Dairies. *See* the attached

**Application No.: 10/646,852**  
**Filing Date: August 22, 2003**

history of Fonterra Co-Operative Group LTD, which can be found at <http://www.fonterra.com/wps/wcm/connect/fonterracom/fonterra.com/our+business/fonterra+at+at+glance/about+us/our+history>. Therefore, Applicant respectfully submits that Carr is not a proper reference under 35 U.S.C. § 103 to at least Claims 38, 2-8, 10-13, 16, and 27.

Further, as discussed above Carr fails to teach or suggest all of the features of Claim 38 explicitly or inherently. Accordingly, Applicant respectfully request withdrawal of these rejections of Claims 38, 2-8, 10-13, 16, and 27.

Even assuming *arguendo* that Carr is a proper reference under § 103 to Claims 17-22, Carr does not render Claims 17-22 obvious. As discussed above, Carr does not disclose the features of Claim 38 explicitly or inherently. Therefore, Carr as modified by the Examiner does not disclose “adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein”. This is more than an obvious variation of the disclosure of Carr. Carr discloses adding salt to milk to form MPC with increased solubility in cold water. The skilled artisan would understand that there are different concerns regarding modifying protein to enhance cold water solubility versus emulsification properties. There is no disclosure or reason to modify the process of Carr to improve emulsification properties and thus there is no reason to modify Carr as suggested by the Examiner.

Further, Carr teaches away from improving emulsification properties. As discussed above, any protein conformation maximizing solubility must fold the non-polar amino acids deep into the protein interior, essentially masking the inherent incompatibility of polar and non-polar compounds. Positioning the non-polar amino acids within the protein interior renders these sections incapable of simultaneously interacting with fat. Unable to interact with the fat, these proteins *cannot* effectively act as emulsifiers. Therefore, the disclosure of Carr regarding enhanced solubility teaches away from enhanced emulsification properties. Accordingly, Applicant requests withdrawal of this rejection for at least this reason.

Moreover, modifying the MPC of Carr to improve the emulsification properties would adversely affect the cold water solubility of the MPC because of the interaction of non-polar

**Application No.: 10/646,852**  
**Filing Date: August 22, 2003**

amino acid groups and water. This change would render Carr unsatisfactory for its intended purpose, to produce MPC with enhanced cold water solubility. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Accordingly, Applicant respectfully requests withdrawal of the rejection for at least this reason.

In addition, for the reasons discussed above, the modification proposed by the Examiner would change the principle of operation of Carr. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Accordingly, Applicant respectfully requests withdrawal of the rejection for at least this reason.

Sadowsky does not make up for the deficiencies of Carr. Accordingly, Applicant respectfully requests withdrawal of this rejection.

The Examiner also found that “[t]he new claims are not seen to influence the conclusion of unpatentability previously set forth.” Office Action at page 3. Applicant respectfully disagrees. Claims 39-42 recite “wherein the first food product comprises high fat cream”, “wherein the high fat cream comprises 70% fat or greater”, “wherein the first food product comprises plastic cream” and “wherein the plastic cream comprises about 80% fat”, respectively. Carr and Sadowsky also fail to disclose these features. For example, Carr fails to disclose forming a first food product comprising high fat cream or plastic cream. Example 9 of Carr discloses forming a milk solution containing 5.36% fat. Carr at page 12, line 18. Sadowsky also fails to disclose this feature. For example, Examples 1 and 2 of Sadowsky disclose forming a slurry with 8.4% and 3.9% fat respectively. Further, Carr and Sadowsky are incapable of forming such a cream because the proteins lack the enhanced emulsification properties that allow formation of higher fat foot products.

This is more than an obvious variation of Carr and Sadowsky. There are different processing concerns for forming a high fat food product as recited in Claims 39-42, thus there would be no reasonable expectation of success for modifying Carr and Sadowsky to produce the

**Application No.: 10/646,852**  
**Filing Date: August 22, 2003**

recited food products. Accordingly, Applicant respectfully requests withdrawal of the rejection of these claims for at least this reason.

For the reasons discussed above, Carr fails to anticipate or make obvious Claims 39-42.

**The Combination of Carr and Sadowsky Does Not Make Claims 33-37 Obvious**

Claims 33-37 stand rejected under 35 U.S.C. § 103 as unpatentable over Carr in view of U.S. Patent No. 6,358,551 to Sadowsky.

Applicant notes that Claims 43-45, which stand rejected as anticipated or made obvious by Carr, depend from Claim 33, which stands rejected as unpatentable in view of Carr and Sadowsky. Applicant requests clarification.

Claim 33 recites in part “homogenizing the combined milk and fat to produce cream”. Sadowsky fails to disclose a method for making cream. In contrast Sadowsky discloses a method for incorporating concentrated milkfat into milk to form a slurry. Col. 5, ll. 30-50. Sadowsky discloses that “[g]enerally, the amount of concentrated milkfat added to the first portion of the reduced-fat raw milk is about 4 to about 10 percent.” Col. 5, ll. 43-45.

Example 1 of Sadowsky discloses forming a slurry with 8.4% fat. Example 2 of Sadowsky discloses forming a slurry with 3.9% fat. The slurries disclosed in Sadowsky do not contain enough milkfat to qualify as a cream under any of the FDA Standards of Identity promulgated in 21 C.F.R. § 131. For example, the FDA Standards of Identity state that heavy cream (21 C.F.R. § 131.150) contain not less than 36% milkfat, light cream (21 C.F.R. § 131.155) contain not less than 18% milkfat and not more than 30% milkfat, and light whipping cream (21 C.F.R. § 131.157) contain not less than 30% milkfat and not more than 36% milkfat.

Therefore, Sadowsky fails to disclose “homogenizing the combined milk and fat to produce cream” as recited in Claim 33. Further, this is more than an obvious variation of Sadowsky. There is also no reason to modify Sadowsky to produce a cream.

Carr fails to make up for the deficiencies of Sadowsky. Accordingly, Applicant respectfully requests withdrawal of this rejection.

For the reasons discussed above, the combination of Carr and Sadowsky fails to make Claim 33 obvious. Accordingly, Applicant respectfully requests withdrawal of the rejection of

**Application No.: 10/646,852**  
**Filing Date: August 22, 2003**

Claim 33. Additionally, Applicant submits that Claims 34-37 and 43-45, are not made obvious by Carr/Sadowsky, not only because they depend from Claim 33, but also on their own merit.

The Examiner also found that “[t]he new claims are not seen to influence the conclusion of unpatentability previously set forth.” Office Action at page 3. Applicant respectfully disagrees. Claims 43-45 recite “wherein the cream comprises more than 36% fat”, “wherein the cream comprises high fat cream”, and “wherein the cream comprises plastic cream”, respectively. Carr and Sadowsky also fail to teach these features. For example, Carr fails to disclose forming a first food product comprising high fat cream or plastic cream. Example 9 of Carr discloses forming a milk solution containing 5.36% fat. Carr at page 12, line 18. Sadowsky also fails to disclose this feature. For example, Examples 1 and 2 of Sadowsky disclose forming a slurry with 8.4% and 3.9% fat respectively. Further, Carr and Sadowsky are incapable of forming such a cream because the proteins lack the enhanced emulsification properties that allow formation of higher fat food products.

This is more than an obvious variation of Carr and Sadowsky. There are different processing concerns for forming a high fat food product as recited in Claims 39-42, thus there would be no reasonable expectation of success for modifying Carr and Sadowsky to produce the recited food products. Accordingly, Applicant respectfully requests withdrawal of the rejection of these claims for at least this reason.

**No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not

**Application No.: 10/640,852**  
**Filing Date: August 22, 2003**

reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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